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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/569,556

02/27/2006

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P29315

7641

7055 7590 11/16/2009  
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EXAMINER

LEVINE, JOSHUA H

ART UNIT

PAPER NUMBER

3774

NOTIFICATION DATE

DELIVERY MODE

11/16/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com  
pto@gbpatent.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/569,556	<b>Applicant(s)</b> OGISO, MAKOTO	
	<b>Examiner</b> JOSHUA LEVINE	<b>Art Unit</b> 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6,9-19 and 22-26 is/are pending in the application.
- 4a) Of the above claim(s) 3,4,11-13,15,16,23 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,6,9,10,14,17-19,22,25 and 26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05/30/2006</u>  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. This office action is responsive to the preliminary amendment filed on 02/27/2006. As directed by the amendment: claims 1, 5, 9-12, 17, 19, 22-23, 25-26 have been amended, claims 7-8 and 20-21 have been cancelled, and no new claims have been added. Thus, claims 1-6, 9-19, 22-26 are presently pending in this application.

### ***Election/Restrictions***

2. Applicant's election with traverse of Group 1, Species A, Subspecies 1 in the reply filed on 09/28/2009 is acknowledged. The traversal is on the ground(s) that while the restriction is supported by PCT Rule 13.1, it is silent with respect to 37 C.F.R. 1.475. This is not found persuasive as the applicant does not argue the examiner's application of lack of unity under P.C.T. rule 13.1.

3. The previous action was not set forth properly as Group I and Group II do share a common technical feature of a porous structure impregnated with bone powder. However, Smestad (4430760) disclosed a porous structure impregnated by bone powder (see rejection to claim 1). Therefore, there is no unity of invention between these groups as the corresponding technical features do not define a contribution over the prior (see MPEP 1801).

4. The common technical feature between species A and B is a porous structure communicating with an outer surface. No unity of invention between these groups as the corresponding technical features do not define a contribution over the prior in light of Smestad (4430760) ((see rejection to claim 1, see MPEP 1801).

Art Unit: 3774

5. The common technical feature between subspecies 1 and subspecies 2 is a porous surface layer. No unity of invention between these groups as the corresponding technical features do not define a contribution over the prior in light of Smestad (4430760) ((see rejection to claim 10, see MPEP 1801).

6. Furthermore, Claims 9 and 22 were improperly set forth as belonging to species A and are therefore withdrawn from the species restriction.

Claims 3, 4, 11, 12, 13, 15, 16, 23 and 24 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group, species, and subspecies, there being no allowable generic or linking claim. Applicant timely traversed the restriction election requirement in the reply filed on 09/28/2009.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 2 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The dimension implied by the limitation “1 or more” is unclear. For the purposes of examination, the examiner will consider the density to have 1 or more **pores** per area.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 3774

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 5-6, 9, 10, 14, 17, 19, 22, and 25-26 are rejected under 35

U.S.C. 102(b) as being anticipated by Smestad (4430760).

11. Regarding claim 1, Smestad disclosed a porous matrix (porous casing, column 1 lines 59) made of a biocompatible material (casing is biocompatible, column 2 lines 59-60) impregnated with fine bone powder (demineralized particulate, column 1 line 57) obtained by pulverizing living bones and/or teeth (bone or dentin particulate, column 1 lines 60-61).

12. Regarding claims 5-6 and 19, Smestad disclosed wherein said biocompatible material is at least one selected from the group consisting of polymers (microporous polymer, column 3 line 9).

13. Regarding claims 9 and 22, Smestad disclosed wherein said fine bone powder has an average diameter of 50  $\mu\text{m}$  or less  $\mu\text{m}$  (embodiments have particles sizes down to 40  $\mu\text{m}$ , column 3 lines 25-27).

14. Regarding claim 10, Smestad disclosed wherein the entire structure is porous (porosity permits permeation **throughout** the implant, column 4 lines 1-3).

15. Regarding claims 14 and 25, Smestad disclosed an artificial bone (used as bone tissue, column 4 lines 24-25) comprising the bone-powder-impregnated, porous structure recited in claim 10.

16. Regarding claim 17, see claim 1 for further explanation. The examiner considers the roughened surface matrix to be roughened via the porous structure disclosed in claim 1.

Art Unit: 3774

17. Regarding claim 26, Smestad disclosed an artificial dental root (craniofacial bone, column 4 lines 28-29) comprising the bone- powder-impregnated, surface-roughened structure recited in claim 17. The examiner considers Smestad et al. to disclose a dental root as Smestad et al. teaches a dentin filled implant for use in repairing craniofacial bone.

***Claim Rejections - 35 USC § 103***

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. Claims 2 and 18 rejected under 35 U.S.C. 103(a) as being unpatentable over Smestad (4430760) in further view of Smith et al. (PG Pub no. 20040253279).

20. Regarding claims 2 and 18, Smestad disclosed all the elements of the claim including wherein it has fine communicating pores having an average diameter of 0.005-50  $\mu\text{m}$  (embodiments have particles sizes down to 40  $\mu\text{m}$ , column 3 lines 25-27) in its entire body (porosity permits permeation throughout the implant, column 4 lines 1-3), said fine communicating pores being open on an outer surface of said porous structure (outer membrane is porous, column 3 lines 36-38) except a structure with a density of 1 or more pores per an area of 50  $\mu\text{m}$  x 50  $\mu\text{m}$ .

Smith et al. teach a porous structure (porous bone substitute, paragraph 31) with a density of 1 or more pores per an area of 50  $\mu\text{m}$  x 50  $\mu\text{m}$  (porosity up to 95% with pore sizes in the range of 15-150 micrometers, paragraph 23). It would have been obvious

Art Unit: 3774

to one of ordinary skill in the art at the time of the invention to include the pore density of Smith et al. for the purpose of encouraging fibro-vascular ingrowth and osteoid formation (paragraph 43).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOSHUA LEVINE whose telephone number is (571)270-5413. The examiner can normally be reached on Monday-Thursday 7:30am-5:00pm ETA.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JOSHUA LEVINE/  
Examiner, Art Unit 3774

/William H. Matthews/  
Primary Examiner, Art Unit 3774